

NOV 18 2003

K021478

510(k) Summary
Delta Shoulder

DePuy, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581

A. Contact Person:

Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs
(574) 371-4905

B. Device Information:

Proprietary Name:	Delta Shoulder
Common Name:	Shoulder Prosthesis
Classification Name and Regulatory Class:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented: Class II per 21 CFR §888.3660
Product Code:	87 KWS

C. Indications for Use:

A Delta Total shoulder prosthesis is indicated for use in:

Grossly rotator cuff deficient joint with severe arthropathy or a previous failed joint replacement with a grossly rotator cuff deficient joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional Deltoid muscle is necessary to use the device.

The metaglene component is HA coated and is intended for cementless application with the addition of screws for fixation. All other components are intended for cemented use only.

D. Device Description:

The Delta Shoulder prosthesis is a modular total shoulder prosthesis that was designed specifically for use in patients with non-functional rotator cuffs. The articulation of this design is "inverted" compared to traditional total shoulder prosthesis. Unlike traditional total shoulder prosthesis, the Delta Shoulder is designed such that the "ball" of the articulation is incorporated into the glenoid prosthesis, and the "cup" of the articulation is incorporated in the humeral prosthesis. The distal surface of the metaglene components are coated with a hydroxyapatite coating (HA) and are intended to be used with 4 metaglene screws for fixation.

E. Substantial Equivalence:

The substantial equivalence of the Delta Shoulder is substantiated by its similarity in indications for use, design, sterilization and packaging to the Biomet Bio-Modular and Bipolar Shoulder (K992119 and K991585), and the Global Advantage Shoulder (K992065).

The determination of substantial equivalence for this device was based on a detailed device description, design rationale, product testing, literature and conformance with voluntary performance standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 18 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K021478

Trade/Device Name: Delta Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: August 25, 2003
Received: August 27, 2003

Dear Dr. Weissman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

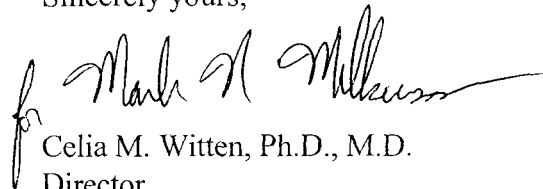
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Dina L. Weissman, J.D.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known)
Device Name

K021478
Delta Shoulder

Indications for Use

A Delta Total shoulder prosthesis is indicated for use in:

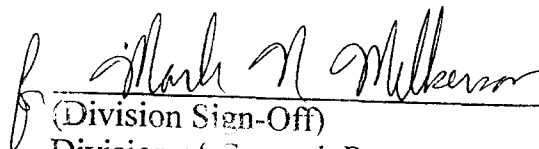
Grossly rotator cuff deficient joint with severe arthropathy or a previous failed joint replacement with a grossly rotator cuff deficient joint.

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K021478

Prescription Use _____
(Per 21 CFR §801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)